

08/796,578 02/06/97



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/796,578	02/06/97	DRIZEN	A 22890-XX

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EXAMINER

HARRISON, R

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/01/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/796,578

Applicant(s)
Drizen et al

Examiner
Robert H. Harrison

Group Art Unit
1616



☒ Responsive to communication(s) filed on Mar 12, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-10, 12-21, 23-37, and 39-44 is/are pending in the application.

Of the above, claim(s) 10, 12-21, 23-28, 37, and 39-44 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-9, and 29-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Receipt is hereby acknowledged of applicants' amendment filed as of March 12, 1998.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1616.

Applicant's election with traverse of Group I, claims 1-9 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search required for the Groups I-IV is co-extensive and thus would not be a serious burden on the Examiner. This is not found persuasive because the Examiner has given sufficient reason why there is distinctness between the method claims Groups II and IV and the product or composition claims Groups I and III. The Examiner is persuaded to the extent of rejoining Groups I and III. However, the distinctness for the method claims is seen as proper. However, the Examiner would consider rejoining the method claims were the product claims to be finally held allowable and the method claims amended to depend from or are required to have the product or composition within their scope and do not introduce any issues of 101, 112, 102 and/or 103. With regard to the search required for the respective groups, it is the position of the Examiner that the search must be extended to include not only topical formulations but also any formulations which have the required overall structure in the

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composition and that does not exclude compositions which have an intended use for oral as well as subcutaneous routes among others.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-28 and 37-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

Claims 1, 3-9 and 29-36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The phrase "average molecular weight" is vague and indefinite since for high polymers such descriptive language renders the claim indefinite absent an indication on how the average molecular weight was determined such as by number average molecular weight, weight average molecular weight and the like.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note that only those issues set forth in this Office action need apply.

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Claims 1, 3-9 and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al. (U.S. Patent No. 5,143,724).

This rejection is maintained for reasons stated already of record in the last Office action mailed as of January 16, 1998 as set forth on pages 7 and 8.

Applicants' arguments filed March 12, 1998 have been fully considered but they are not deemed to be persuasive.

Applicants traverse, arguing that the term "average molecular weight" is not indefinite because a number average molecular weight is always implied in the absence of any indication to the contrary. This argument is respectfully traversed since this is a bald statement unsupported by not one shred of evidence. In fact, quite the opposite is actually the truth. No polymer has ever been made wherein all molecules have exactly the same molecular weight. The molecules will be of a wide variety of molecular weights. Furthermore, there are four kinds of molecular weights. Each numerical value is different for the same polymer. The differences are dependent upon the molecular weight distribution. They are number average, viscosity average, weight average, and Z average. The same kind of molecular weight of these four listed above will have different values if different methods are used to measure it. Comparisons are valid only if homogeneous polymers are used as

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the known polymer with which comparisons are made. It is the position of the Examiner that the facts in this case point towards the critical nature of these polymers as argued by applicants. Thus, based on the facts in this case, one of ordinary skill in this art would not be reasonably apprised if the claims are infringed. To recapitulate, it is well established that different techniques or bases for determining the average molecular weights of polymers result in differing values, representing, principally, a number average molecular weight, a weight average molecular weight, a viscosity average molecular weight and a Z average molecular weight. In given circumstances, wide differences exist between the resultant average molecular weights determined by the various bases. See, for instance, Billmeyer, Textbook of Polymer Science, Interscience Publishers, New York, 1962, paragraph bridging pages 66 and 67. Since no particular basis is stated coupled with the fact that substantial variation in the resultant average molecular weight can be attributed to the selection of a particular basis, clearly establishes the indefiniteness of a recitation of an average molecular weight value without an indication of the basis used to determine such figure. See also Kirk-Othmer, Encyclopedia of Chemical Technology, 2nd Edition, Volume 16, 1968, pages 242-253, especially 242 and 245-251. Again, it is the position of the Examiner that based on the facts

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in this case, one of ordinary skill in the art would not be reasonably apprised if the claims are infringed. The Examiner is also aware that claims are given their broadest reasonable interpretation consistent with the specification. For example, if in the instant specification a statement such as "molecular weight when mentioned in the specification and claims means number average molecular weight" would be viewed as effectively limiting the claims to number average molecular weight. Accordingly, it is not required that "number average molecular weight" or any other molecular weight determination be specifically mentioned in the claims. The manner in which this issue is addressed depends upon the facts in each application. Since the Examiner sees no basis for shedding light on how the average molecular weight is determined, the Examiner suggests applicants file a continuation-in-part which amends the application to include the manner in which the average molecular weight was determined or other appropriate action.

The Examiner would also point out that the Nakajima article (cited with this Office action) supports the Examiner's contention that the numbers representing average molecular weight for the same polymer differs considerably depending upon the method that was used for its determination. The article compares number average molecular weight and weight average molecular weight for the same polymer. In summary, the Examiner is not of

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the opinion that the term "average molecular weight" as it is conventionally used in the polymer art is definite in accordance with 35 U.S.C. § 112, second paragraph.

Applicants traverse, arguing that the prior art does not render the instant claims prima facie obvious because applicants' invention is directed to achieving transdermal sustained release drug delivery and that applicants' claims are narrowly defined with respect to the negative charged to nonionic charged polymers. Moreover, applicants assert that the two phase matrix in the prior art is different from the instant polymer mixture. These arguments are respectfully traversed since applicants have provided mere argument without any supporting facts. Argument of counsel does not take the place of evidence on the record. Arguments of counsel are not evidence unless they are an admission. It remains the position of the Examiner that the instant claims are rendered prima facie obvious since all limitations of the claims have been met by the reference applied against the instant claims and it is not necessary for an inherent property or characteristic to be recited in the reference when the overall structure of the compositions in the reference is the same as those claimed.

Applicants argue that the instant invention achieves unexpected results vis-a-vis the prior art. This argument is respectfully traversed for the reasons that arguments of counsel

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cannot take the place of evidence on the record and that applicants have provided no proof that the claimed inventions achieve any unexpected results vis-a-vis the disclosure of '724. Accordingly, the instant case of prima facie obviousness has been maintained.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H. Harrison, whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9:30 A.M. to 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jose Dees, can be

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reached on (703) 308-4628. The fax telephone number for this Group Art Unit is (703) 305-5433 or (703) 305-5408.

Any inquiry of general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0096.

Robert H. Harrison
Robert H. Harrison
Primary Examiner
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RHHarrison:cdc
June 23, 1998